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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,669	10/14/2003	James F. Zucherman	KLYCD-05007US1	3387

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Sheldon R. Meyer
FLIESLER DUBB MEYER & LOVEJOY LLP
Fourth Floor
Four Embarcadero Center
San Framcosco, CA 94111-4156

EXAMINER	
PRIDDY, MICHAEL B	

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5P

Office Action Summary	**Application No.** 10/684,669	**Applicant(s)** ZUCHERMAN ET AL.	
	Examiner Michael B Priddy	**Art Unit** 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 27 December 2004.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16,31-56 and 58-160 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) See Continuation Sheet is/are rejected.

7)☒ Claim(s) See Continuation Sheet is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/01/2004; 12/10/2004 + 02/10/2005

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 1,4-9,12-16,31,34-38,41,44-48,51,52,54,56,58,59,63-69,71,72,74-82,84-86,90-96,98-111,115-119,122,123,126,128-132,134-136,140-145 and 147-160.
Continuation of Disposition of Claims: Claims objected to are 2,3,10,11,32,33,39,40,42,43,49,50,53,55,57,60-62,70,73,83,87-89,97,112-114,120,121,124,125,127,133,137-139 and 146.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-9, 15, 16, 31 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Cauthen (U.S. 6,179,874). Cauthen teaches an intervertebral implant comprising: a first plate 22 adapted to mate to a first vertebral body, the first plate 22 including an elongated socket 106 having first S1 and second S2 sidewalls that are substantially perpendicular to the second plate; a second plate 20 adapted to mate to a second vertebral body, the second plate 20 including an elongated ball 100 with the elongated ball 100 having a top surface TS and first W1 and second W2 elongated sidewalls and third W3 and fourth end W4 walls that are substantially perpendicular to the second plate 20; and the top surface TS slopes from the third end wall W3 to the fourth end wall W4 (the Examiner takes the position that a curved surface has a slope that changes with position).

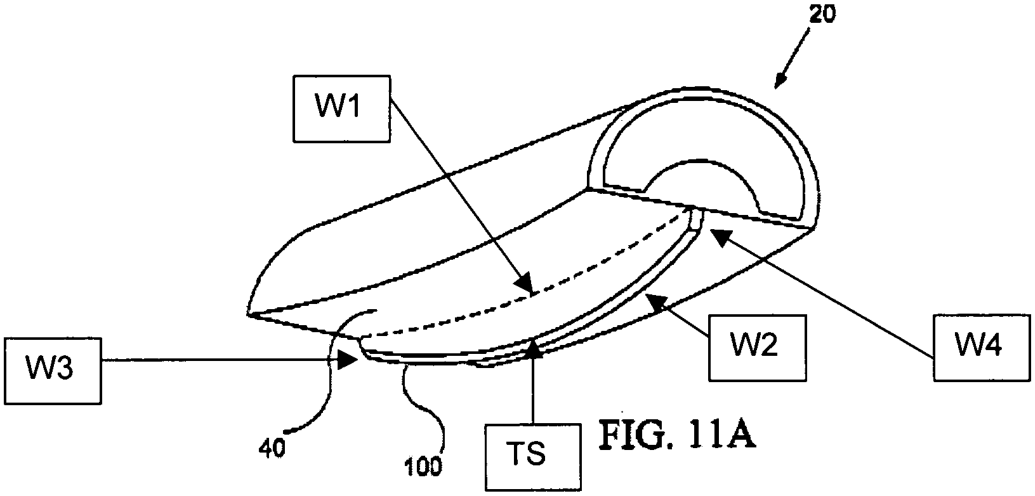


FIG. 11A

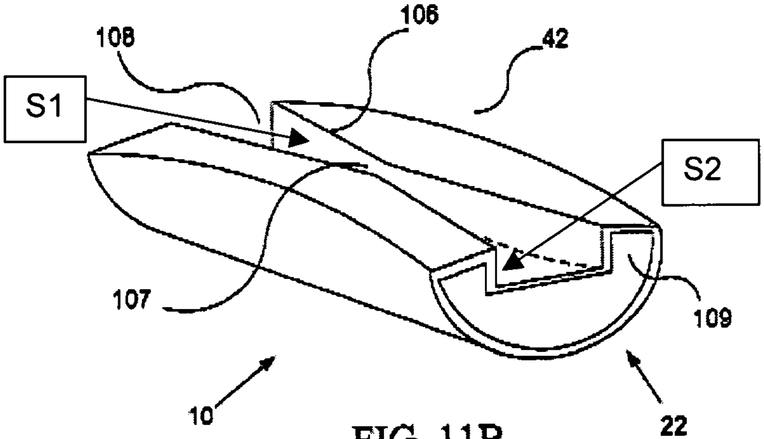


FIG. 11B

Claims 51, 52, 54, 56, 58, 59, 63-69, 71, 72, 74-78, 82, 84-86, 90-96, 98-107, 132, 134-136, 140-145, 147-156, 158 and 159 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramadan et al. (U.S. 6,517,580). Ramadan et al. teaches an intervertebral implant adapted to be implanted between a pair of vertebral bodies, said implant comprising: a first plate 3 having a keel with a profile of a right triangle and a socket 7; and a second plate 2 having a keel and a ball 5 formed thereon and having an upper surface 6, wherein the ball has sidewalls perpendicular to a surface 2_1 of the second plate 2; wherein the second plate 2 has a channel 18 located on an inner surface 2_2 of the second plate 2 and formed adjacent the ball 5 on three sides; wherein the keels are not in the same plane; wherein the socket 7 has exterior walls EW which are perpendicular to a surface 3_1 of the first plate 3 and interior walls 8 which are not perpendicular to a surface 3_1 of the first plate 3; wherein the first plate 3 has a ridge 3_2 adjacent the socket 7 on three sides; wherein the upper surface of the ball slopes from a center laterally to each side and from one side to another (the Examiner has taken the position that a curved surface has a slope that changes with position).

With regard to claims 103-107, 158 and 159, it is noted that the device of Ramadan et al. appears to be substantially identical to the device claimed, although produced by a different process, therefore the burden is upon the Applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

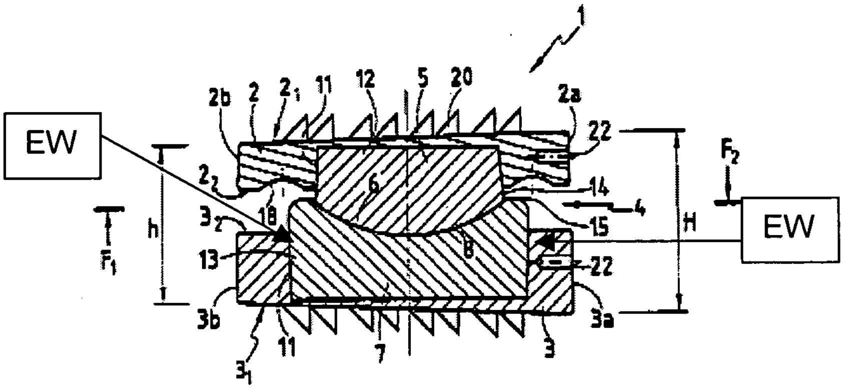


FIG.1

Claim 108 is rejected under 35 U.S.C. 102(b) as being anticipated by Cauthen. Cauthen teaches an intervertebral implant comprising: a first plate 22 having a socket 106 formed thereon; and a second plate 20 having a ball 100 formed thereon, wherein the socket 106 has three walls W and an open end O.

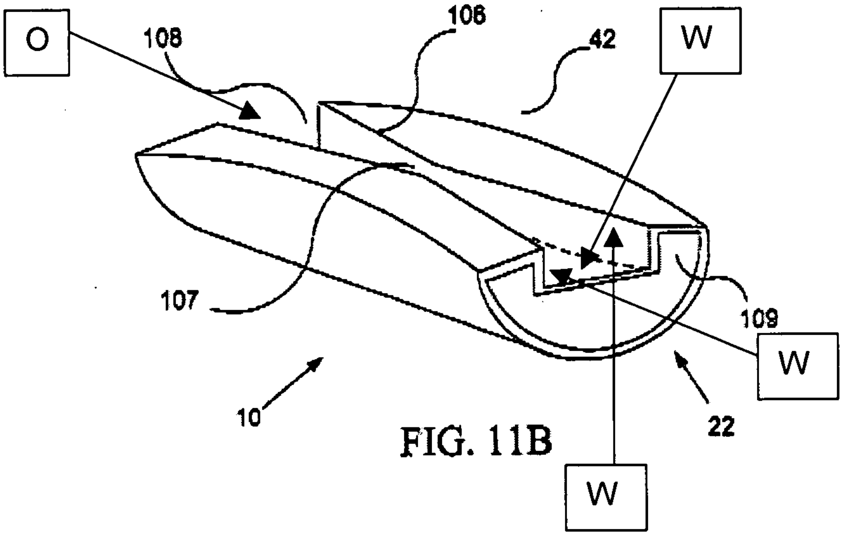
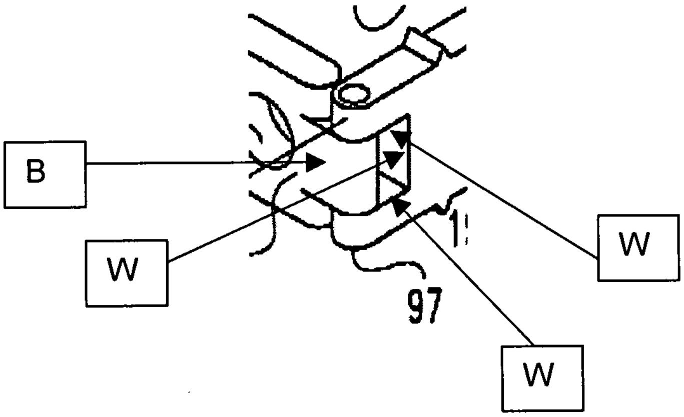


FIG. 11B

Claims 108-111, 115, 116, 119, 122, 123, 126 and 128 are rejected under 35 U.S.C. 102(b) as being anticipated by Foley et al. (U.S. 6,193,757). Foley et al. teaches an intervertebral implant comprising: a first plate 212 having a socket formed thereon; and a second plate 214 having a ball B formed thereon, wherein the socket has three walls W (a marked up copy of Fig. 24a has been used below for illustration purposes. It is the Examiner's understanding that the ball and socket of Fig. 24a are equivalent to those of Fig. 25) perpendicular to surface 212 and an open end; wherein the first and second plates have keels 224 (protrusions/ridges) which are aligned; and wherein the second plate 214 has a channel (formed between any two adjacent keels/protrusions/ridges). Concerning the limitations of claim 128 which requires the vertebral bodies be accessed posteriorly, it is noted that the device of Foley, et al. appears to be substantially identical to the device claimed, although produce by a different process (accessed posteriorly), therefore the burden is upon the Applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31, 37, 38, 41, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen. Cauthen teaches an intervertebral implant comprising: a first plate 22 adapted to mate to a first vertebral body, the first plate 22 including an elongated socket 106 having first S1 and second S2 sidewalls that are substantially perpendicular to the second plate; a second plate 20 adapted to mate to a second vertebral body, the second plate 20 including an elongated ball 100 with the elongated ball 100 having a top surface TS and first W1 and second W2 elongated sidewalls and third W3 and fourth end W4 walls that are substantially perpendicular to the second plate 20; and the top surface TS slopes from the third end wall W3 to the fourth end wall W4 (the Examiner takes the position that a curved surface has a slope that changes with position). Hence Cauthen teaches all of the limitations of the present invention except a *pair* of first plates and a *pair* of second plates.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include more than one of the implant of Cauthen (and thereby more than one of each plate), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 1, 4-6, 9 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen in view of Viart et al. (FR 2805985). Cauthen teaches an intervertebral implant comprising: a first plate 22 adapted to mate to a first vertebral body, the first plate 22 including an elongated socket 106 having first S1 and second S2 sidewalls that are substantially perpendicular to the second plate; a second plate 20 adapted to mate to a second vertebral body, the second plate 20 including an elongated ball 100 with the elongated ball 100 having a top surface TS and first W1 and second W2 elongated sidewalls and third W3 and fourth end W4 walls that are substantially perpendicular to the second plate 20; and the top surface TS slopes from the third end wall W3 to the fourth end wall W4 (the Examiner takes the position that a curved surface has a slope that changes with position). Hence Cauthen teaches all of the limitations of the present invention except a first keel extending from the first plate and substantially perpendicular to the elongated socket and adapted to engage a first vertebral body, and a second keel extending from the second plate and substantially perpendicular to the elongated ball and adapted to engage a second vertebral body.

Viart et al. (FR 2805985) teaches an intervertebral disc prosthesis having an upper plate 2 and a lower plate 3 both of which have keels "7 to allow said plates to become anchored in the upper and lower end plates of the vertebral bodies of the overlying and underlying vertebrae." (lines 7-9 of column 3) It would have been obvious to one of ordinary skill in the art at the time of the present invention to supply keels as taught by Viart et al. to the first and second plates of Cauthen to aid in the anchoring of the plates in the upper and lower end plates of the vertebral bodies of the overlying and underlying vertebrae.

Claims 31, 34-36, 41 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen in view of Viart et al. as applied to claims 1, 4-6, 9 and 12-14 above, and further in view of *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. The combination taught by Cauthen and Viart et al. discloses all of the limitations of the present invention except a *pair* of first plates and a *pair* of second plates.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include more than one of the implant of combination of Cauthen and Viart et al. (and thereby more than one of each plate), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 51, 76, 78-81 and 157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramadan et al. Ramadan et al. teaches an intervertebral implant adapted to be implanted between a pair of vertebral bodies, said implant comprising: a first plate 3 having a keel with a profile of a right triangle and a socket 7; and a second plate 2 having a keel and a ball 5 formed thereon and having an upper surface 6, wherein the ball has sidewalls perpendicular to a surface 2_1 of the second plate 2; wherein the second plate 2 has a channel 18 located on an inner surface 2_2 of the second plate 2 and formed adjacent the ball 5 on three sides; wherein the keels are not in the same plane; wherein the socket 7 has exterior walls EW which are perpendicular to a surface 3_1 of the first plate 3 and interior walls 8 which are not perpendicular to a surface 3_1 of the first plate 3; wherein the first plate 3 has a ridge 3_2 adjacent the socket 7 on three sides; wherein the upper surface of the ball slopes from a center laterally to each side and from one side to another (the Examiner has taken the position that a curved surface has a slope that changes with position). Hence Ramadan teaches all of the limitations of the present invention except the first plate further comprises a pair of first plates and the second plate further comprises a pair of second plates.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Ramadan et al. to have a plurality of first plates and a plurality of second plates, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 108, 110, 115, 117, 118 and 129-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al. in view of In re Dailey and Eilers, 149 USPQ 47 (1966). Foley et al. teaches an intervertebral implant comprising: a first plate 212 having a socket formed thereon; and a second plate 214 having a ball B formed thereon, wherein the socket has three walls W (a marked up copy of Fig. 24a has been used below for illustration purposes. It is the Examiner's understanding that the ball and socket of Fig. 24a are equivalent to those of Fig. 25) perpendicular to surface 212 and an open end; wherein the first and second plates have keels 224 (protrusions/ridges) which are aligned; and wherein the second plate 214 has a channel (formed between any two adjacent keels/protrusions/ridges). Hence, Foley et al. discloses the claimed invention except for the protrusions have the profile of right triangles.

It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the protrusions/keels 224 of Foley et al. with the profile of right triangles, since Applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming a protrusion on an intervertebral implant. In re Dailey and Eilers, 149 USPQ 47 (1966).

Concerning the limitations of claims 130 and 131 which requires the pair of plates be implanted either such that there is a medial gap between them or such that they abut each other, it is noted that the device of Foley, et al. appears to be substantially identical to the device claimed, although produce by a different process (accessed posteriorly), therefore the burden is upon the Applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Claim 160 is rejected under 35 U.S.C. 102(e) as being anticipated by Ramadan et al. (U.S. 6,517,580). Ramadan et al. teaches an intervertebral implant adapted to be implanted between a pair of vertebral bodies, said implant comprising: a first plate 3 having a keel with a profile of a right triangle and a socket 7; and a second plate 2 having a keel and a ball 5 formed thereon and having an upper surface 6, wherein the ball has sidewalls perpendicular to a surface 2_1 of the second plate 2; wherein the second plate 2 has a channel 18 located on an inner surface 2_2 of the second plate 2 and formed adjacent the ball 5 on three sides; wherein the keels are not in the same plane; wherein the socket 7 has exterior walls EW which are perpendicular to a surface 3_1 of the first plate 3 and interior walls 8 which are not perpendicular to a surface 3_1 of the first plate 3; wherein the first plate 3 has a ridge 3_2 adjacent the socket 7 on three sides; wherein the upper surface of the ball slopes from a center laterally to each side and from one side to another (the Examiner has taken the position that a curved surface has a slope that changes with position). Hence Ramadan teaches all of the limitations of the present invention except the specific degree measures claimed.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the joint of Ramadan such that it had a forward bending movement of 10 degrees; a rearward bending movement of 5 degrees; a right lateral bending movement of 5 degrees; a left lateral bending movement of 5 degrees; a right axial rotation of 3 degrees; and a left axial rotation of 3 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Allowable Subject Matter

Claims 2, 3, 10, 11, 32, 33, 39, 40, 42, 43, 49, 50, 53, 55, 57, 60-62, 70, 73, 83, 87-89, 97, 112-114, 120, 121, 124, 125, 127, 133, 137-139 and 146 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 02/10/2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (571) 272-4717. The examiner can normally be reached on Mon.-Fri. 10 a.m. - 7 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael B. Priddy
Michael B. Priddy
March 18, 2005

Kevin Shaver
KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700